

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,185	<b>Applicant(s)</b> HAUPERT, GARNER T.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
     4a) Of the above claim(s) 20-31 and 33-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 32 is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/9/07</u>  | 6) <input type="checkbox"/> Other: ____                           |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-37 are pending.

Applicants' amendment filed July 9, 2007 is acknowledged. Applicant's response has been fully considered. Claims 1, 11, 20, 21, 25, 26, 30-32, 36 and 37 have been amended. Claims 20-31 and 33-37 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1-19 and 32 are examined.

Regarding additional species election on the ATPase, target cells and disorders in Group I, applicants' response has been considered and applicants' arguments are found persuasive. Since all the species for these items have been examined in the previous Office Action, the species election is withdrawn.

### **Withdrawn Claim Rejections - 35 USC § 112**

2. The previous rejection of claims 1-19 and 32 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 12 in the amendment filed July 9, 2007.

Regarding the rejection of claims 12-14 under 35 U.S.C. 112, second paragraph (see paragraph 4 of previous Office Action) for the term "derived from". The rejection should include claim 11, since claim 11 recites the term "derived from". Claims 13-14 are dependent from claim 12, which is dependent from claim 11, thus claims 13-14 are also included for the rejection.

### **Withdrawn Claim Rejections - 35 USC § 103**

Art Unit: 1656

3. The previous rejection of claims 1, 4, 5, 8-10, 15, 16 and 19 under 35 U.S.C. 103(a) as being unpatentable over Anner *et al.* (Am. J. Physiol. 258, F144-153 (1990)) in view of Hauptert, Jr. (The Sodium Pump, Steinkopff & Darmstadt (pub), N.Y. pp732-742 (1994)), is withdrawn in view of applicants' response at pages 12-14 in the amendment filed July 9, 2007.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-14 are directed to an assay for screening a test substance for HIF inhibitory activity of an ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  by measuring the amount of the isotopic  $\text{Rb}^+$  present in the liposomes or the cells in the presence of the test substance or HIF under comparable conditions, where the liposomes or the cells contains an ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$ , the ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  is isolated from a target cell, the target cell is obtained from a patient exhibiting a disease state that is related to dysfunction of the ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$ , and the response of the target cell to the substance can be determined.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical

genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates the ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  can be obtained from various target cells, e.g., the target cells are obtained from a patient exhibiting a disease state that is related to dysfunction of the ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  (page 6), the specification does not describe how to determine whether the target cell responds to the test substance in the claimed assays, and what is the correlation between the screening a test substance that exhibits HIF inhibitory activity of an ouabain-resistant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  and the response of the target cell to the test substance. The lack of description on the response of the target cell to the test substance in the claimed assays, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention,

Art Unit: 1656

in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-14 are indefinite because of the use of the phrase "thereby determining whether said target cell will respond to the test substance". The term cited renders the claim indefinite, it is not clear how to determine whether the target cell responds to the test substance in the claimed assay, and what is the correlation between the screening a test substance that exhibits HIF inhibitory activity of an ouabain-resisitant  $\text{Na}^+\text{-K}^+\text{-ATPase}$  and the response of the target cell to the test substance. Claims 12-14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

***Conclusion***

6. Claims 11-14 are rejected; and claims 1-10 and 32 are free of art.

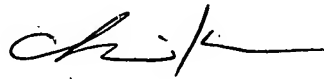
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

September 21, 2007